Internal Audit Check list			
PRODUCTION			
Created:	17/May 1995	**Audit No 15**	VOP 08
Revised:	23 October 2017		Page 1 of 5
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.1.3	**Infrastructure** The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	
VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	
Viamed Ltd ISO13485:2016 6.3	**Infrastructure** The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information	

	systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained	
Viamed Ltd ISO13485:2016 7.5.1	**Control of production and service provision** Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.	

	NOTE Further information can be found in ISO 19011.	
Viamed Ltd ISO13485:2016 8.2.6	**Monitoring and measurement of product** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures. Evidence of conformity with the acceptance criteria shall be maintained. The identity of the person authorizing release of product shall be recorded (see 4.2.5). As appropriate, records shall identify the test equipment used to perform measurement activities. Product release and service delivery shall not proceed until the planned and documented arrangements have been satisfactorily completed. For implantable medical devices, the organization shall record the identity of personnel performing any inspection or testing.	

	QUESTION:	**RESPONSE**	**Y/N**
1	Check that each job for production has its own unique worksheet in the ducket.		
2	Does the worksheet contain all the relevant information.		
3	Check that all jobs are kept in an appropriate duckets.		
4	Check that jobs awaiting assembly are in the correct area.	Production jobs are usually released one at a time. These are worked on at time of release.	
5	Verify that all parts are correctly scanned to the production build by the operator. Use the PS production number from a production job in a ducket or from the all jobs list and then put it into - Production – Parts pick. This list can then be compared to the stock procedure – Parts List to Build batch. Check 5 to see if what is scanned matches what is required. 1 2 3 4 5		
6	Check that the operating procedure is with the job, and is the latest issue.	Intrastats links to production COPS	N/A
7	Verify that the operator has adequate training and / or experience.	Training Audit	N/A
8	Verify that there is adequate tooling to complete the task.		
9	Check that completed jobs are in the correct area.		

10	Verify that all the relevant information is entered into Intrastats. Check 5 production jobs. Use the same as below to find a barcode ID from each Production job and check its QA history. 1 2 3 4 5		
11	Check the Start Job List in Production to see if they are all valid. Review any older than a month. List any below.		
12	Check the Production in Production List in production. The list shows what is in and at what stage it is at. Review any older than a month. List any below.		
13	Check that finished product is placed in the correct area for test.	Tested at time of production	
14	Is there adequate storage and working facilities.		
15	Is the production area in a tidy and workable state.		
16	Can resources be improved to facilitate process control.		

Sub Processes Linked to Audit

Review the below processes tasks and audits and ensure they are completed in a timely manner.

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7727** To carry out Audit 15 Production Viamed		28 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7775** To carry out Audit 15 Production VST		175 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Production Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7736** When a new production is needed we the production job to the list of procedures. Check to make sure that every new job has a procedure linked to it.	553 Goods In	554 Managing Director	Freq 3 Risk 4 Overall 12	Task 1M Audit 3M	
PROCESSID **7737** Review the Production List, check and list those items that were started more than 30 days ago have not been through QA. Audit is carried out and production is reviewed and chased at this point.	556 Goods In	557 Managing Director	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
PROCESSID **7738** Production Review, Identify any production jobs taking a long amount of time	551 Goods In	552 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	